Patent Claims

1. Transdermal therapeutic system (TTS) comprising an active-substance-containing cement matrix, characterized in that the cement matrix contains a hot-meltable adhesive in which the active substance, Rotigotine ((-)-5,6,7,8-tetrahydro-6-[propyl[2-(2-thienyl)ethyl)amino]-1-naphthol), is dispersed and partly or completely dissolved.

2. TTS as in claim 1, for which the active-substance-containing cement matrix is produced by metering the Rotigotine into the solvent-free melt of the cement matrix at a temperature of between 70°C and 200°C.

3. TTS as in claim 1 or 2, in which the hot-meltable adhesive consists of a mixture of an amine-resistant silicone adhesive and at least one suitable softener.

4. TTS as in claim 3, in which the softener is an organic wax.

5. TTS as in claim 3 or 4, in which the softener is ceresine or ozokerite.

6. TTS as in one of the preceding claims, in which the percentile proportion of the Rotigotine in the cement layer is 4-40 weight%.

7. TTS as in one of the preceding claims, in which the percentile proportion of the Rotigotine in the cement layer is 9-30 weight%.

8. TTS as in one of the claims 1-6, in which the percentile proportion of the Rotigotine in the cement layer is 20-40 weight%.

9. TTS as in one of the preceding claims, in which the Rotigotine is present as the biocatalytic base.

10. TTS as in one of the preceding claims, in which the active-substance-containing cement matrix additionally contains an internal-phase component selected from the group of

    (a) hydrophilic or amphiphilic polymers
    (b) hydrophilic or amphiphilic copolymers
    (c) mixtures of (a) and/or (b) with pharmaceutically acceptable softeners
    (d) condensates from glycerin and fatty acids or polyols
    (e) suitable mixtures of the components (a)-(d)

11. TTS as in claim 10, in which the internal-phase component is selected from the group of polysaccharides, substituted polysaccharides, polyethylene oxides, polyvinyl acetates, polyvinyl pyrrolidones, copolymers from polyvinyl pyrrolidone and (poly)vinyl acetate, polyethylene glycol, polypropylene glycol, copolymers from ethylene and vinyl acetate, glycerin-fatty acid ester as well as mixtures of polyvinyl alcohol with glycerin.

12. TTS as in claim 1, characterized in that the cement matrix comprises

    (a) 50-99 weight% of a hot-meltable adhesive
    (b) 4-40 weight% Rotigotine
    (c) 0-40 weight% of an internal-phase component
    (d) 0-10 weight% other adjuvants

13. TTS as in claim 12, for which the hot-meltable adhesive (a) selected is
    (a1) an EVA adhesive
    (a2) an SXS adhesive, or
    (a3) a mixture of
        (i) 70-99 weight% of an amine-resistant silicone adhesive
        (ii) 1-30 weight% of a suitable softener

14. TTS for the continuous transdermal administration of Rotigotine, characterized in that, for a period of at least 5 days following its application on human skin, said TTS induces in the patient an average plasma concentration of 0.4 to 2 ng per ml Rotigotine.

15. TTS as in claim 14, characterized in that the TTS induces in the patient an average plasma concentration of 0.4 to 2 ng/ml Rotigotine for a period of at least 7 days.

16. TTS as in one of the preceding claims, characterized in that the Rotigotine is transported through the skin at a steady-state flux rate of 200-300 μg per hour.

17. TTS as in one of the claims 14-16, said TTS comprising a Rotigotine-containing layer, characterized in that the active-substance-containing layer
    (a) contains Rotigotine in a percentile proportion of at least 20 weight%,
    (b) has a Rotigotine content of at least 2.0 mg/cm^2, and
    (c) optionally contains an organic wax and/or internal-phase component in an amount sufficient to retard the release of the active substance.

18. Method for producing a TTS that encompasses a cement matrix containing Rotigotine as the active substance, characterized in that prior to their lamination the components of the cement matrix are melted and homogenized, solvent-free, at temperatures between 70°C and 200°C.

19. Method as in claim 18, characterized in that the components of the cement matrix are melted and homogenized in an extruder.

20. Use of Rotigotine in the production of a TTS by the hot-melt method, characterized in that the Rotigotine is introduced, at temperatures between 70°C and 200°C, in the TTS cement matrix that has been premelted without solvents.

21. Method or use as in one of the preceding claims, whereby the hot-melting process takes place at temperatures between 120°C and 160°C.

22. Method or use as in one of the preceding claims, whereby the Rotigotine is introduced, in the cement-matrix melt, in its solid state.

23. Method or use as in one of the preceding claims, whereby the cement matrix, produced by the hot-melting process, contains Rotigotine at a purity level of at least 98% as measured by HPLC at 220 nm and 272 nm.